

REMARKS

Claims 30, 36, and 37-45 are pending. Claims 1-29 and 31-35 have been canceled. New Claims 38-45 have been added.

Support for Claim 38 is found at page 22, line 3.

Support for Claim 39 is found at page 22, line 3.

Support for Claim 40 is found at page 22, line 3.

Support for Claim 41 is found at page 13, lines 13-15, page 23, line 23, and page 23, line 23 to page 24, line 1.

Support for Claim 42 is found at page 19, line 13.

Support for Claim 43 is found at page 23, lines 13-15.

Support for Claim 44 is found at page 13, line 13 and page 23, line 8..

Support for Claim 45 is found at page 13, line 13.

No claims fee is believed to be due; however, the Commissioner is hereby authorized to charge any additional claims fees which may be required to Deposit Account No. 14-0629.

Rejection under 35 USC §112, first paragraph

The Examiner has rejected Claim 37 under 35 USC §112, first paragraph, as allegedly failing to comply with the written description requirement, in that it contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor had possession of the claimed invention at the time the application was filed. The rejection is respectfully traversed.

The Examiner alleges Claim 37 lacks adequate descriptive support in the originally filed application for the limitation that the "concentration of the complex exceeds 0.05% by volume." The Examiner asserts that because the disclosure says nothing as to the concentration of silver citrate in solution, there is no support for claiming a concentration greater than 0.05% by volume. Applicant respectfully disagrees.

The specification at page 13, line 19, states “[t]he electrolytically generated silver has a concentration of in excess of 0.05% by volume.” Moreover, original claim 30 recites “an aqueous solution of silver citrate in a solution of citric acid and water wherein the concentration of silver citrate exceeds 0.05% by volume,” establishing further support for the limitation in claim 37.

The Examiner is respectfully requested to withdraw the rejection to Claim 37 under 35 USC §112, first paragraph.

Rejection under 35 USC §102(b)

The Examiner has rejected Claims 30 and 36 under 35 USC §102(b) as allegedly being anticipated by Srivastava *et al.* The rejection is respectfully traversed for the reason that Srivastava does not disclose the claimed composition.

The Examiner asserts that Srivastava explicitly discloses a solution of 0.5% silver citrate. Further, he asserts the Applicant’s specification teaches that prior art silver citrate has a solubility limit of 285 ppm (0.0285%) and that Applicant’s claimed complex (silver dihydrogen citrate) has a higher solubility. Allegedly, because Srivastava reports a concentration of silver citrate greater than the prior art solubility of 285 ppm, the silver citrate of Srivastava must be the silver dihydrogen citrate of the present application.

As the attached Declaration of Dr. David Pullman indicates, “it is highly unlikely that Srivastava’s solution was truly 0.5% in concentration.” Dr. Pullman provides scientific support for his conclusion that Srivastava’s silver citrate was either “only partially dissolved, so the actual concentration in solution was less than 0.5%” or “0.5% was a typographical error.” These conclusions are bolstered by noting that Srivastava’s gauze dipped in silver citrate had no bactericidal activity as would be expected of an 0.5% solution of silver citrate.

Applicant’s specification discloses bactericidal data for silver dihydrogen citrate (Tables 7-9). One of the organisms for which the Applicant provides data is *Staphylococcus aureus*. This species was also reportedly tested by Srivastava. As indicated in table 8 of the present application, a solution comprising 0.000408% (4.08 ppm) of silver dihydrogen citrate is shown to have a 6.0 log₁₀ kill of this microorganism after 1 hour. Srivastava, at Table 2, page 211,

discloses “[o]n the other hand observations for 30 min., 1, 2 and 4 hours in sample 7 [0.5% silver citrate] and control sample have been omitted because even after 24 hours of contact with treatment 7 the organisms multiplied.” This inconsistency is not noted or considered by the Examiner.

Further, the Examiner points out that Srivastava’s solution is 17.5 times more concentrated than the literature reported limit of 285 ppm for “typical prior art silver citrate”. If this were true, one would expect Srivastava’s 0.5% silver citrate solution to have at least the same effectiveness against *Staphylococcus aureus* as Applicant’s 0.000408% solution. Moreover, in his abstract, Srivastava indicates that silver citrate has no bactericidal activity. Faced with this inconsistency, the Examiner nevertheless chose to rely on Srivastava’s disclosure as anticipatory of Applicant’s claimed silver dihydrogen citrate.

The Examiner continues in his rejection by proffering a series of unsubstantiated hypotheses in support of his argument that Srivastava’s silver citrate is the same as Applicant’s silver dihydrogen citrate, concluding “such a species must necessarily be present.” The Examiner has also asserted “[a]s for the presence of citric acid. . .the present claim language requires no more than that which would be present in equilibrium between silver and citrate.” Applicant believes that this conclusion is erroneous.

As explained by Dr. Pullman in his Declaration, “it is known by those of ordinary skill in the art that the term ‘silver citrate’ (also known as trisilver citrate) refers to a salt having the formula $\text{Ag}_3\text{C}_6\text{H}_5\text{O}_7$. . . ”(Pullman Declaration at paragraph 9). Dr. Pullman references Exhibits B through F which indicate that that which is commonly referred to as “silver citrate” in the prior art is “trisilver citrate.”

Importantly, Dr. Pullman provides data from Electrospray Ionization Mass Spectrometry which he performed on commercially available “silver citrate” and silver dihydrogen citrate (AxenohlTM obtained from Applicant). Referring to these spectral data, Dr. Pullman states that “the two compositions are distinct.” (Pullman Declaration at paragraph 23).

In Srivastava, there is no disclosure of how the tested solutions 1-8 were made, nor the source of any of their components. The absence of this critical information, especially in light of the inconsistencies between the results reported by Srivastava and the Applicant, would have

been expected to call into question the scientific accuracy of Srivastava's disclosure. Applicant does not desire to speculate on the composition of Srivastava's solution 7, but it was clearly not silver dihydrogen citrate; otherwise, at a concentration of 0.5%, Srivastava would have reported bactericidal activity instead of concluding "silver citrate showed . . . no bactericidal activity."

In conclusion, Srivastava does not disclose silver dihydrogen citrate as recited in Claims 30 and 36 and therefore does not anticipate these claims. The Examiner is respectfully requested to withdraw the rejection of Claims 30 and 36 under 35 USC §102(b).

Double Patenting

The Examiner has rejected pending Claims 30 and 36 under the judicially created doctrine of obviousness-type double patenting over Claim 1 of U.S. Patent Application Serial No. 10/846,221 (hereinafter "the '221 Application"). The '221 Application is abandoned; therefore the Examiner's rejection of Claims 30 and 36 of this application is rendered moot.

The Examiner has rejected Claims 30 and 36 under the judicially created doctrine of obviousness-type double patenting over Claims 1-7 of U.S. Pat. 6,197,814 to Arata, issued March 6, 2001 (hereinafter "Arata '814"). Upon indication that claims in the present application are allowable, Applicant will respond as appropriate to this rejection in light of a comparison between the allowed claims and those of the Arata '814.

The Examiner has rejected the pending claims under the judicially created doctrine of obviousness-type double patenting over Claims 1, 5 and 8 of U.S. Patent Application Serial No. 10/434,742 ("the '742 Application") and over Claim 1 of U.S. Patent Application Serial No. 11/060,013 ("the '013 Application"). As neither the '742 Application or the '013 Application has yet issued, these rejections are considered premature and a response will be held in abeyance.

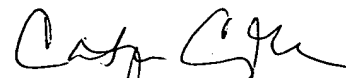
CONCLUSION

Pursuant to the above Remarks and the Declaration under 37 CFR §1.132 of Dr. David Pullman, reconsideration and allowance of the pending application is believed to be warranted.

ATTORNEY DOCKET NO. 16200.0006U4
APPLICATION NO. 10/600,006

The Examiner is invited and encouraged to directly contact the undersigned if such contact will enhance the efficient prosecution of this application to issue.

Respectfully submitted,
NEEDLE & ROSENBERG, P.C.

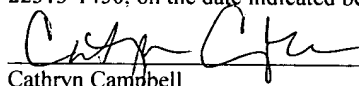


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CERTIFICATE OF MAILING UNDER 37 CFR § 1.8

I hereby certify that this correspondence and the documents mentioned therein are being deposited with the United States Postal Service in an envelope addressed to: MAIL STOP RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA. 22313-1450, on the date indicated below



Cathryn Campbell

3-27-07
Date